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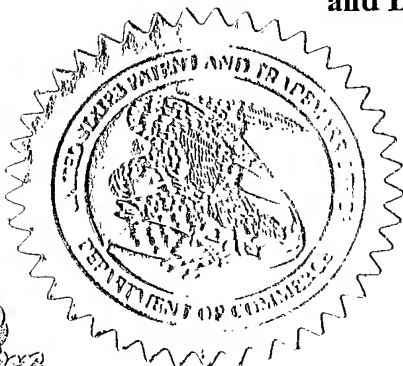
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Additional inventors are being named on the _____ separately numbered sheets attached hereto					
TITLE OF THE INVENTION (500 characters max)					
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[Page 1 of 2]

Respectfully submitted,

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# **Medical Navigation System Based on differential sensor**

## **Provisional Patent**

Written by:  
Shlomi Ben-ari

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## 1. Scope

This paper provides a description of a novel intravascular navigation system based on differential radiation sensing. It is written in order to be submitted as a provisional patent.

## 2. Background

Existing medical imaging systems (e.g. MRI, MRA, CT, Nuclear imaging) provide a means for detection of malformation in body tissues. In most cases, reaching the lesion for biopsy or treatment requires a surgical procedure that causes damage to healthy tissue.

An intravascular approach can often be utilized for reaching the suspected lesion using a catheter. A navigation system that locates the catheter tip is required in order to guide the operator to the exact location of the lesion during the procedure.

### 2.1. The medical need

The identified need is a system that tracks the location of a medical tool (such as a catheter tip, needle, laparoscopic tool etc) relative to some external reference frame.

This system is referred as a Tracking system or Navigation system.

#### 2.1.1. Required tracking system characteristics

- Provide 3 dimensional tracking of a small element
  - Sensor size 0.1 to 1 mm diameter, Goal: below 0.1 mm
- Accurate tracking - less than 1 mm error, in the harsh environment of standard operating arena
  - In presence of metal elements and tools
  - EM Radiation emitted by medical equipment
- Does not require clear line of sight to the tracked element
- Does not require rigid connection between the tracked element and the outside world
  - To allow intravascular procedures
- Does not expose the patient or the operator to harmful doses of radiation
- Wireless tracked element is preferred

### 2.2. Prior art medical tracking solutions

#### 2.2.1. Electro Magnetic Tracker

Most of the existing intravascular navigation systems are based on the so called EM Tracker (Electro Magnetic). The EM tracker is based on generating a quasi static magnetic field within the volume of interest. The tracked element senses the field in its vicinity and its location is calculated based on its measurement of the local field.

EM tracker disadvantages:

- The EM tracker is found to be vulnerable to EMI (Electro Magnetic Interference) due to emission from PC monitors and other medical equipment.
- The EM tracker accuracy is degraded due to metallic elements in the vicinity of the tracker.
- Tracking a tip of a catheter requires routing wires along the catheter.

### **2.2.2. Optical Tracker**

Optical tracking is based on analyzing images of a number of cameras viewing the tracked element (Light source or Reflector).

Optical Tracker disadvantages:

- Applicable only to situations where the tracked element is rigidly attached to a visible light source or reflector. Thus not applicable to intravascular navigation
- Requires a clear path from the cameras to the tracked element.

### 3. The proposed solution for intravascular tracking system

The proposed tracking solution is based on utilizing a radiation form to which the human body is relatively transparent (e.g. gamma rays, low frequency RF, etc). The tracked element either emits or reflects the radiation of interest, and its location within the body is measured by sampling the radiation from outside the body.

The tracked element can be a small amount of radioactive material, a miniature RF transmitter or an RF reflector.

#### 3.1. Concept overview

The proposed tracker concept is to utilize a set of tracking modules. Each tracking module provides one angle defining a plane within which the tracked element lies. By combining the information from several modules at different locations, the system can accurately calculate the location of the tracked element in three dimensions.

The following section provides a bottom up description of the tracking system, starting with the basic tracking modules and from there to the system level concepts.

##### 3.1.1. Basic Tracking Module (BTM)

###### 3.1.1.1. BTM Structure

Following is a conceptual view of the Basic tracking module.

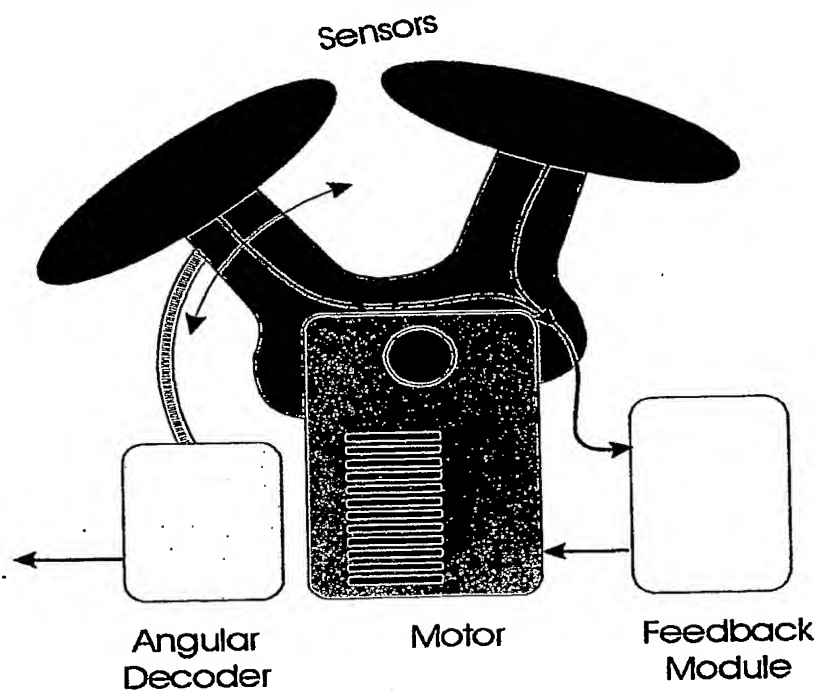


Figure 1 : Basic Tracking Module – conceptual view



The Basic Tracking Module (referred as BTM) is composed of the following:

- 2 radiation detectors.  
Geometrically arranged such that the ratio between their readings is proportional to the relative location of the radiation source (in at least one axis)
- Moving mechanical mount that can rotate (or translate) the above sensors.
- Feedback mechanism.  
The function of this module is to rotate (or translate) the sensors until their readings are identical. Digital or Analog Signal processing may be utilized for this purpose.
- Orientation (or position) decoder.  
The function of this device is to measure the actual orientation (or position) of the sensors in which the readings are identical.

#### 3.1.1.2. BTM Functionality

The BTM output is the angle (about the axis of the BTM) from the BTM to the radiator.

#### 3.1.2. Tracker System

The tracker system's objective is to calculate the position of the tracked element (radiator).

Following is a schematic illustration of such a system:

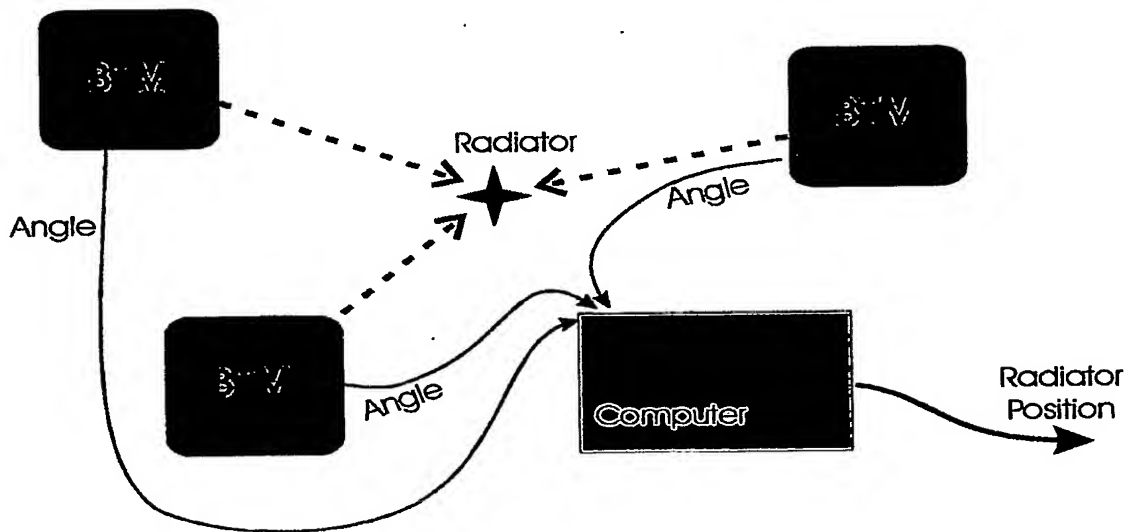


Figure 2 : Tracker system structure

The tracking system is composed of several Basic Tracking Modules (BTMs), each providing the angle from it to the radiator about one axis.

Knowing the position and axis orientation of all of the BTMs in the system, one can calculate the radiator's position in space relative to the BTMs.

Each BTM output defines a plane in which the radiator resides; this plane is defined by the measured angle. It is known that the intersection of three planes defines a singular point in space. Thus, a system comprising of three BTMs is able to locate the radiator.

If more than three BTMs are installed, it is possible to improve the overall accuracy and to provide a Figure of Merit along with the position (FOM - estimation of the tracking error).

### 3.2. Tracker Implementation examples

As mentioned above, the concept of tracking a radiator using a dispersed set of 1-axis trackers can be implemented by utilizing a variety of radiation types. For example:

- Radio Frequency (RF)
- Nuclear Gamma emission
- Visible light
- Sound waves
- Etc.

The first two examples seem to be applicable to intravascular tracking systems. And will be depicted in more detail in the following sections.

#### 3.2.1. RF Tracker

The RF tracker is intended to locate a radio frequency radiator or reflector that is placed on a medical tool. The system concept is the same as described above.

The differential sensor for RF is described in the following section.

##### 3.2.1.1. Typical RF antenna gain

Every RF antenna has some level of sensitivity in almost every direction. A typical plot of the antenna gain versus the angle from the antenna's central axis is illustrated in Figure 3.

This figure illustrates how much the antenna increases (or decreases) the signal received from each direction.

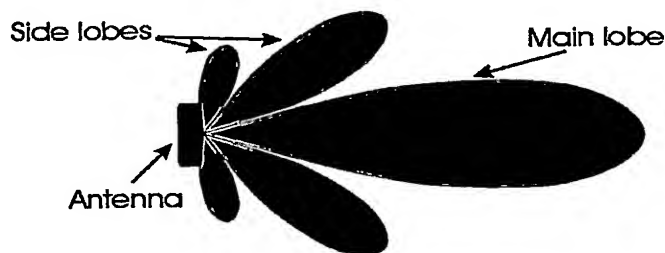


Figure 3 : Typical RF antenna main and side lobes shape

##### 3.2.1.2. Differential RF sensor arrangement

Two antennas can be arranged in a way that their main lobes intersect as in the illustration below:

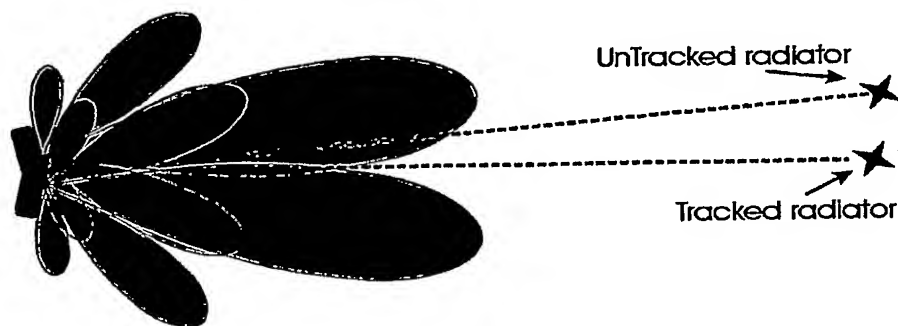


Figure 4 : Differential RF sensor

The antenna cluster can be rotated until the amplitude of the signal is identical in the two antennas. Any movement of the emitter will result in a difference between the readings. Mechanical measurement of the antenna's orientation in this situation provides the angle from the antenna to the emitter (or reflector) about the axis of rotation of the antenna.

### 3.2.2. Nuclear tracker

The Nuclear tracker is intended to locate a gamma ray radiator that is placed on a medical tool. The system concept is the same as described above.

The differential sensor for gamma rays is described in the following section.

Radioactive matter emits particles in random directions. The existing gamma ray sensors can not detect the origin of the radiation i.e. the direction of the ray is unknown. The sensor can become direction-sensitive by installing a collimator on top of it. By doing so, most of the radiation is obscured and thus, the sampling time is increased substantially.

However, the following differential sensor can determine the direction to the radiation source about one axis without obscuring the majority of the incoming radiation (allowing a short sampling time).

#### 3.2.2.1. Differential gamma ray sensor arrangement

Following is an illustration of the nuclear differential sensor.

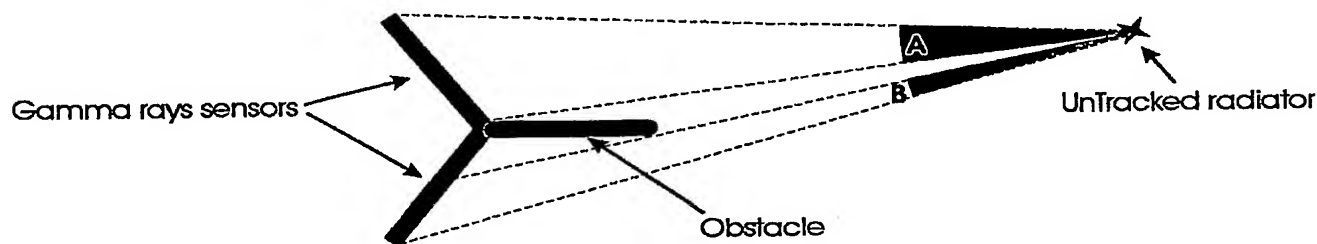


Figure 5 : Nuclear differential sensor

Since the radiation is emitted randomly, the number of particles that are sensed by each sensor is proportional to the spatial angle of the sensor, as viewed from the emitter.

For example, in Figure 5, the red sensor will detect more particles per time unit than the blue sensor, since angle A is larger than B. (assuming accumulating enough data to overcome the quantization noise)

Only when the sensor is pointing directly to the emitter, will the two readings be identical.

As in the RF tracker described above, the sensors cluster can be rotated until the particle hit rate is identical for the two sensors. Mechanical measurement of the sensor's orientation in this situation provides the angle from the sensor to the emitter about the axis of rotation of the sensor.

#### **3.2.2.2. Nuclear tracker implementation guidelines**

- The radioactive material may be spread over few millimeters (~10) in order to reduce the maximal local radiation level below the allowed threshold
- Utilizing radioactive materials with different radiation wavelength will allow tracking two point simultaneously, and thus calculating the orientation of the tracker element
- The sensor geometry shall be designed in such manner to maximize the angular sensitivity i.e. maximize the difference between the two sensors cause by angular change

### **4. System Application example**

The proposed tracking solution can be applied to a variety of medical systems.

Three examples of those systems are described further in this document:

- Intravascular navigation system.
- Extra vascular navigation system with flexible catheter.
- Laparoscopy operation guiding system.

#### **4.1. Intravascular navigation system**

##### **4.1.1. System Overview**

The tracking system shall be integrated into an imaging system (MRI, CT, Etc). A common coordinates system is defined for both systems. The suspected lesion location is measured relative to this coordinate system utilizing the imaging system.

Based on the imaging data, a three dimensional model of the region of interest is generated and presented online to the operator.

During the procedure, the actual catheter tip location is presented on the image in such manner that allows the operator to navigate the catheter directly to the required location.

Accurately reaching a suspected lesion can be utilized for performing biopsy or applying treatment such as:

- Inject medication
- Brachy therapy
- RF radiation
- Freezing
- Stent application
- Etc.

Such a system is most effective in treating lesions with limited or difficult access such as:

- Brain tumors
- Brain aneurisms

- Liver tumors

#### 4.1.2. System block diagram

The following figure illustrates the top level block diagram of the intravascular navigation system:

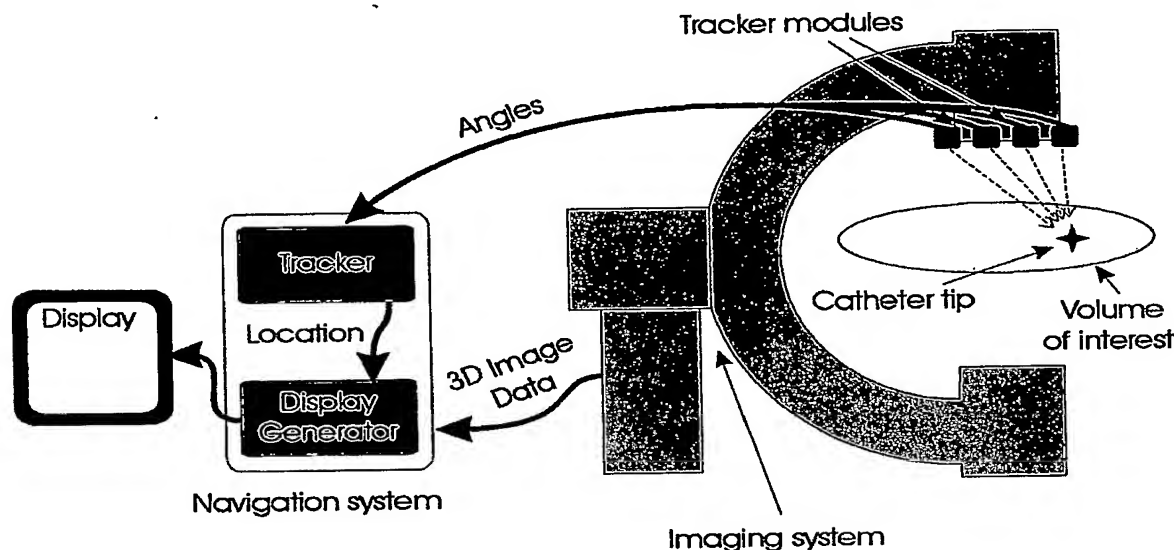


Figure 6 : Intravascular Navigation System block diagram

#### 4.1.3. System highlights

The catheter guidance can be performed inside the imaging system based on updating imaging data or outside the system, based on past images.

Using such system for intravascular treatments will:

- Minimize the damage to healthy tissue
- Minimize the required operator skills
- Expand the treatable population
- Increase the number of successful procedures.